SUPPORTING STATEMENT

Substances Prohibited from Use in Animal Food or Feed, 21 CFR Part 589

A. JUSTIFICATION

1. Circumstances Making the Information Collection Necessary

Section 701(a) (21 U.S.C. 371(a)) of the Federal Food, Drug, and Cosmetic Act (the act) gives us the authority to issue regulations for the efficient enforcement of the act. On June 5, l997, we issued a final rule which amended 21 CFR 589.2000 to provide that animal protein derived from mammalian tissue (with some exclusions) is not generally recognized as safe (GRAS) for use in ruminant feed, and is a food additive subject to certain provisions of the act. The rule placed general requirements on persons that manufacture, blend, process and distribute products that contain or may contain protein derived from mammalian tissue, and feeds made from such products.

We took this action because epidemiological evidence gathered in the United Kingdom suggested that bovine spongiform encephalopathy (BSE), a progressively degenerative central nervous system disease, is spread to ruminant animals by feeding protein derived from ruminants infected with BSE. While BSE had yet to be diagnosed in the United States, measures were necessary to prevent the establishment and amplification of this fatal disease in this country and thereby minimize any risk which might be faced by animals and humans.

In 2003, two cows tested positive for BSE, one in Canada and the other in the state of Washington. An epidemiological investigation and DNA test results confirmed that the Washington state cow was born and most likely became infected in Alberta, Canada, prior to Canada's 1997 implementation of a ban on feeding mammalian protein to ruminants. Several BSE positive cows were found in Canada from 2004-2006; in June of 2005, a 12-year-old beef cow, born and raised in Texas, tested positive for BSE. This was the first instance of BSE infection of a cow native to the United States.

The cases of BSE detected in Canada and the United States provide evidence of the risk of BSE in North America. The U.S. and Canadian feed bans implemented in 1997 were intended to address uncertainty about whether BSE was present in the cattle population of either country. While we continue to believe that compliance with the feed regulation has provided strong protection against the spread of BSE, the agency believes that the recent cases are an indication that additional animal feed protections are needed. Therefore, we believe that it was appropriate to propose certain additional measures in October 2005. More than 800 comments were received from industry, trade associations, government entities, and consumers. The final rule, which published April 25, 2008 (73 F.R. 22720), prohibits the use of certain cattle origin materials in the food or feed of all animals. These materials include the following: (1) the entire carcass of bovine spongiform encephalopathy (BSE)-positive cattle; (2) the brains and spinal cords from

cattle 30 months of age and older; (3) the entire carcass of cattle not inspected and passed for human consumption that are 30 months of age or older from which brains and spinal cords were not removed; (4) tallow that is derived from BSE-positive cattle; (5) tallow that is derived from other materials prohibited by this rule that contains more than 0.15 percent insoluble impurities; and (6) mechanically separated beef that is derived from the materials prohibited by this rule. This is a request for OMB approval of the following information collection requirements:

21 CFR 589.2001 (c)(2)(ii) and (vi)- Recordkeeping – Requirement for renderers that manufacture, process, blend or distribute cattle materials prohibited in animal feed or products that contain or may contain cattle materials prohibited in animal feed, to maintain adequate written procedures specifying how they remove brain and spinal cord from cattle not inspected and passed for human consumption, or how they separate such animals based on whether or not they are 30 months of age or older. Renderers in this category must also maintain records sufficient to track cattle materials prohibited in animal feed to ensure such material is not introduced into animal feed. Records are to be made available for FDA inspection and copying, and are to be retained for a minimum of 1 year.

21 CFR 589.2001 (c)(3)(i) – Recordkeeping – Requirement for renderers that manufacture, process, blend or distribute any cattle materials, to establish and maintain records sufficient to demonstrate that material rendered for use in animal feed was not manufactured from, processed with or does not otherwise contain cattle materials prohibited in animal feed. For renderers that receive cattle materials from a supplier, such records would be considered sufficient if they include either 1) certification or other documentation from the supplier that material supplied to the renderer does not include CMPAF, provided that it includes a description of the segregation procedures used, documentation that the supplier confirms that its segregation procedures are in place prior to supplying any cattle material to the renderer, and records of the renderers periodic review of the suppliers' certification or other documentation. Records are to be made available for FDA inspection and copying, and are to be retained for a minimum of 1 year.

21 CFR 589.2001(c)(3)(i) (A) and (B) – Recordkeeping
Documentation of another method acceptable to FDA, such as third party certification, for verifying that suppliers have effectively excluded CMPAF. Records are to be made available for FDA inspection and copying and are to be retained for a minimum of 1 year.

21 CFR 589.2001(b)(1) and 21 CFR 589.2001(f)—Reporting—New requirement that any foreign country seeking a designation from FDA that such country, due to a low BSE risk in that country, is not subject to the restrictions applicable to cattle materials prohibited in animal feed must submit a written request to the agency. The written request would have to include sufficient scientific evidence to support the claimed BSE

risk status.

2. Purpose and Use of the Information Collection

These records will be subject to inspection by Federal and State agencies to ensure that animal food or feed does not contain protein which may cause the spread of BSE in this country.

3. Use of Improved Information Technology and Burden Reduction

The regulation does not specifically prescribe the use of automated, electronic, mechanical or other technological techniques or other forms of information technology as necessary for use by firms. Firms have the option of using information technology if they wish.

4. Efforts to Identify Duplication and Use of Similar Information

There are no other regulations or Federal agencies that require the development and maintenance of recordkeeping of this nature.

5. Impact on Small Business or Other Small Entities

The reporting & recordkeeping provisions are no more burdensome for small firms than for large. The regulations require all affected parties to maintain the same records. The recordkeeping requirements are based on the risk associated with the product.

6. Consequences of Collecting the Information Less Frequently

If there are no requirements for reporting and recordkeeping, the Agency will have limited means to monitor compliance. Without the ability to monitor compliance, the health of animals and the public may be put at risk.

7. Special Circumstances Relating to the Guideline of 5 CFR 1320.5

All of the reporting requirements are consistent with 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency.

In accordance with 5 CFR 1320.8(d), in the Federal Register of July 28, 2011 (76 FR 45259), a 60-day notice was published for public comment on this information collection. No comments were received that pertained to the information collection burden estimates.

9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide for payment or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents.

Confidentiality of information will be safeguarded within the provisions of FDA's public information regulations in 21 CFR Part 20,

11. Justification for Sensitive Questions.

This information collection does not involve any questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs.

The recordkeeping requirement in proposed § 589.2001(c)(2)(vi) will apply to the limited number of renderers who will handle prohibited bovine material. We estimate that no more than 50 of the approximately 175 rendering firms will be involved in the handling of this material. Although we may consider the distribution records needed to comply with this proposed regulation "usual and customary" and thus not subject to the PRA, we believe there will be burden associated with setting up a system to ensure such records are sufficient to address the proposed recordkeeping requirement. Likewise, although we may consider the records necessary to comply with proposed § 589.2001(c)(3)(i) as "usual and customary" and not subject to the PRA burden accounting, we are including a burden estimate to cover establishment of a system to ensure existing receipt and manufacturing records adequately address this proposed requirement.

There will be a one-time reporting burden to countries that apply to FDA seeking to be designated as not subject to the restrictions applicable to CMPAF (§ 589.2001(b)(1) and (§ 589.2001(f)); these provisions were added in the final rule. We estimate that each country that applies for an exclusion will spend 80 hours putting information together to submit to FDA. Table 1, row 1, of this document presents the one-time burden expected for countries that apply for the exclusion, and row 2 of the Table shows the recurring burden.

12a. Annualized Burden Hour Estimate

Table 1- Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours	Operation & Maintenance Cost
§589.2001(b)(1)[2,]	10	1	10	80	800	40,432[3].
§589.2001(f)	10	1	10	26.4	264	
Total burden					1,064	40,432

[1] There are no capital cost associated with this collection

[2]One time burden

[3]Combined O&M cost for §§ 589.2001(b)(1) & 589.2001(f)

Table 2 -. Estimated Annual Recordkeeping Burden [1]

21 CFR Section	Number of Record keepers	No. of Records per Record keeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours	Operation and Maintenance Cost
589.2001(c)(2)(ii)and (vi) ; 589.2001(c)(3)(i)	175	1	175	20	3,500	$61,985
589.2001(c)(2(ii)	50	1	50	20	1,000	$17,710
589.2001(c)(3(i)(A) and (B)	175	1	175	26	4,550	$80,580
Total					9,050	$160,275

[1]There are no capital cost associated with this burden

Estimated recordkeeping burden and operation and maintenance cost are derived from Agency resources and discussions with affected industry. The rule would require additional measures be taken by renderers that handle CMPAF or products containing CMPAF to ensure that the prohibited materials are not used in animal feed. We believe that the recordkeeping requirements would result in modest additional costs to all renderers as they would only require incremental administrative activities (to modify procedures and periodically review and file) beyond current renderer recordkeeping requirements.

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Compliance Officer	1064	$38	$40,432.

As indicated in Table 1 above, this final rule adds a provision that allows a country to submit an application requesting a designation as not being subject to the new restrictions on the use of CMPAF. Using a total burden of 1,064 hours times the hourly wage of a compliance officer ($38)[1], the estimated cost is $40,432.

13. Estimate of Other Total Cost Burden to Respondents

As indicated in Table 2 above, the total estimated annual recordkeeping O & M costs for the rendering industry is $160,275 (9,050 hours times $17.71/hr.)

14. Annualized Cost to the Federal Government

The final rule may require the expenditure of additional funds by the Federal or State government, but the increased expenditures are not expected to be significant. The tissues that would be included on the list of cattle materials prohibited in animal feed, due to this final rule, may increase the number of inspections or the length of time necessary to inspect an establishment to verify compliance with the new requirements. However, the number of establishments inspected is not expected to substantially change as a result of this rule. All establishments that would be inspected for compliance under § 589.2001 would already be subject to §589.2000 or other federal rules.

However, the final rule will require some additional cost to the government for the review of the estimated 10 applications from foreign governments for country exclusion designation (Table 1 above). The estimated time for reviewing and evaluating these applications by FDA personnel is approximately 50 hours per application. Therefore, the cost to the Federal Government is estimated to be $25,000 (50 hours times $50/hour [GS-13 times 10 applications).

15. Explanation of Program Changes or Adjustments

There were no changes.

16. Plans for Tabulation and Publication and Project Time Schedule

Not applicable.

17. Explain the reasons that display of the expiration date for OMB approval of the information collection would be inappropriate

Not applicable.

18. Exceptions to Certification for Paperwork Reduction Submissions

There are no exceptions to the certification.

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[1]2006 National Industry-Specific Occupational Employment and Wage Estimates, US Department of Labor, Bureau of Labor Statistics (www.bls.gov/oes/current/naics4_325400.thm) $29.27 hourly wage plus 30% adjusted for benefits.